that pages 84-85 of Examiner Owen's search report (Accession Number 1990:11236 in AIDSLINE) are the reference to which he refers. Applicant hereby requests further examination and reconsideration of the application, in view of the foregoing amendments.

Rejection Under 35 U.S.C. § 112

The Examiner rejected claims 1-20 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is the Applicant's position that a person of ordinary skill in the art would be enabled to practice the full scope of the claimed subject matter without the need for unobvious contributions or undue experimentation, taking into account all information available in the prior art. The scope of the claims is commensurate with the scope of the enabling disclosure set forth in the specification, with the specification being read in light of all knowledge readily available in the prior art. Even though some experimentation may be necessary to practice certain embodiments covered by the claims, the Applicant argues that only a reasonable amount of experimentation would be required by a person skilled in the art. The Applicant has supplied six working examples with dosage ranges given and that, given what is already known to and available to the public, is enough to support enablement and to overcome a §112 rejection.

Rejection Under 35 U.S.C. § 102

The Examiner rejected claims 1, 2 and 4 under 35 U.S.C. 102(b) as being anticipated by each of Knupp et al., Lemay et al., Cloyd et al., and Harakeh et al. The Applicant would like to

respectfully point out that Lemay et al., Int. Conf. AIDS, vol 5, 1989 (abstract) does not teach the cortisol blocker ketaconazole (as stated by the Examiner) in combination with the anti-HIV drug Zidovudine (AZT) but rather the cortisol blocker **DHEA** with the anti-HIV drug AZT.

Knupp et al. teaches the coadministering of anti-HIV drug DDI and cortisol blocker ketoconazole. The claims, as amended, will no longer be anticipated by this reference.

Lemay et al. teaches the cortisol blocker DHEA with the anti-HIV drug AZT. The claims, as amended, will no longer be anticipated by this reference.

Cloyd et al. teaches the cortisol blocker phenytoin in combination with the anti-HIV drug AZT. The claims, as amended, will no longer be anticipated by this reference.

Harakeh et al. teaches the cortisol blocker ascorbic acid in combination with the anti-HIV drug AZT. The claims, as amended, will no longer be anticipated by this reference.

The claims, as amended, will no longer be anticipated by any of the references cited above.

Rejection Under 35 U.S.C. § 103

The Examiner rejected claims 3 and 6-20 under 35 U.S.C. 103 as being unpatentable over Devita et al., in combination with Beale and Lemay. Claim 3 is drawn to a composition comprising at least two anti-HIV drugs and a cortisol blocker. Claims 6-20 are drawn to a method for the management of side effects associated with the administration of anti-HIV drug therapy comprising administration to a patient a therapeutically effective amount of at least one cortisol blocker.

The Examiner has stated that Devita et al. teaches combinations of anti-HIV drugs are beneficial in treating HIV infections for several reasons. What Devita does not teach is that anti-HIV drugs can or should be used in combination with anti-cortisol drugs. There is little argument that conventional treatment of HIV infected individuals involves the combination of two or more anti-HIV drugs (the cocktail) but applicant's invention teaches the administration of at least one anti-cortisol drug *in combination* with conventional anti-HIV drug combinations.

The Examiner has stated that Beale teaches anti-cortisol compounds are shown to reduce the catabolic effects associated with AIDS. What Beale does not teach is the use of anti-cortisol drugs in combination with anti-HIV drugs. Beale is directed toward a method for increasing the lean body mass or muscle mass of a mammal in need of increased lean body mass or muscle mass by the administering pyruvate and a cortisol blocker (see column 5, lines 25-29). Applicant's invention, on the other hand, teaches the administration of at least one anti-cortisol drug *in combination* with conventional anti-HIV drug combinations to prevent, reduce or suppress the Cushingoid type symptoms and fat metabolism side effects of anti-HIV drug therapy. The Applicant's invention has the added benefit of treating the side effects of without significant damage to the beneficial therapeutic effects of the anti-HIV drugs (see the instant invention, page 12, lines 16-18). Beale does not discuss anti-HIV drug therapy or its side effects, at all.

The Examiner has stated that Lemay et al. teaches the benefits of combination therapies wherein cortisol blockers' are used in the treatment of HIV. Based upon the limited information available in the abstract provided, the Int. Conf. AIDS meeting paper is reporting an in vitro study in which the ability of DHEA (an anti-cortisol drug) to inhibit the replication of HIV-1 is

discussed. The conclusion of the paper was that DHEA was a "modest selective inhibitor of HIV-1 replication in human lymphocytes and macrophages." The Int. Conf. AIDS meeting paper did not teach (as the Applicant's invention does) the administration of at least one anti-cortisol drug in combination with anti-HIV drugs to alleviate the disfiguring fat deposits that appear as a result of anti-HIV drug therapy (see the instant invention, page 12, lines 9-16). The reference teaches the use of DHEA for reduction in HIV-1 multiplication **not** for treating the side effects of HIV drug cocktails as the Applicant's invention accomplishes.

Devita et al. in combination with Beale and Lemay et al. do not present a *prima facie* case of obviousness. Not one of these references discusses physical symptoms that are similar to Cushings disease that come about due to the administration of anti-HIV drugs and that can be prevented, suppressed or reduced by the administration of at least one anti-cortisol drug and that can, at the same time, be administered without damage to the beneficial therapeutic effects of the anti-HIV drugs being given. It would be an error to reconstruct the Applicant's claimed invention from the prior art by using the Applicant's invention as a blueprint. The selective combination of references based on hindsight should be avoided. Even though a suggestion to modify the three prior art references to produce the claimed invention need not be expressly stated, there must be some implied suggestion to do so. The Applicant does not believe that one skilled in the art would find obvious the invention as a whole based upon the prior art references cited. There is no teaching, suggestion or incentive, in the prior art, to combine the anti-cortisol drug treatment with the anti-HIV drug treatment to decrease the side effects of anti-HIV drugs.

It is respectfully submitted that the present application is now in condition for allowance and such action is earnestly requested.

Respectfully submitted,

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